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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/834,760

04/12/2001

Richard C. Austin

19874-000410

4286

20350

7590

10/31/2006

TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/834,760		AUSTIN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Jon Eric Angell		1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 47-54, 56-59 and 62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-54 and 56-59 is/are allowed.
- 6) ☒ Claim(s) 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Action is in response to the communication filed on 8/14/2006.

The amendment filed 8/14/2006 is acknowledged. The amendment has been entered.

Claims 47-54, 56-59 and 62 are currently pending in the application and are addressed herein.

#### ***Drawings***

The drawings submitted 4/12/2001 remains objected to, for the reasons of record. It is acknowledged that Applicants have indicated that formal drawings will be submitted upon receiving a Notice of Allowance.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 62 is rejected under 35 U.S.C. 102(b) as being anticipated by Vannucchi et al. (Haematologica, Vol. 80, 1995; pages 341-343).

The instant claim is drawn to a method of inhibiting the generation of active thrombin on the surface of a cell within a mammal, the method comprising increasing the expression or activity of an ER resident calcium-binding protein in said cell by administering directly to said

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cell a proinflammatory cytokine, wherein said pro-inflammatory cytokine is interleukin-3 (IL-3) whereby the generation of active thrombin on the surface of said cell is inhibited.

It is noted that the recitation “of inhibiting the generation of active thrombin on the surface of a cell within a mammal” does not have patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, the recitation “increasing the expression or activity of an ER resident calcium-binding protein in said cell” and the recitation “whereby the generation of active thrombin on the surface of said cell is inhibited” are considered functional limitations such that the performing the claimed method steps would necessarily result in the desired function. That is, any method where the claimed methods steps are performed would necessarily result in increased expression or activity of an ER resident calcium-binding protein in the cell and inhibition of the generation of active thrombin on the surface of said cell. Therefore, any teaching of administering the pro-inflammatory cytokine IL-3 to a cell in a mammal in the prior art would anticipate the instant claims.

Vannucchi et al. teaches administering the pro-inflammatory cytokine IL-3 to a cell in a mammal. Specifically, Vannucchi et al. teaches administering recombinant human IL-3 to a 24-year-old man by continuous i.v. infusion. Although Vannucchi does not explicitly teach that the administration of the IL-3 resulted in the increased expression or activity of an ER resident calcium binding protein or inhibition of thrombin generation on the surface of cells in the man,

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the fact that the IL-3 was administered to cells in the mammal would necessarily result in the increased expression or activity of an ER resident calcium binding protein and inhibition of active thrombin generation in the cells contacted by the IL-3.

*Response to Arguments*

Applicant's arguments filed 8/14/2006 have been fully considered.

With respect to the rejection of claims under 35 U.S.C. 112 first and second paragraphs, Applicants arguments, in view of the amendment to the claims, are persuasive and the rejection(s) are hereby withdrawn

With respect to the rejection of claim 62 under 35 U.S.C. 102(b), Applicants respectfully submit that Vannucchi et al. do not disclose all of the elements, features or limitations of amended claim 62. Specifically, Applicants assert that Vannucchi et al. do not teach or suggest that the generation of active thrombin on the surface of the cell is inhibited by the administration of interleukin-3 to the cell.

In response, it is respectfully pointed out that the recitation "whereby the generation of active thrombin on the surface of said cell is inhibited" is considered a functional limitation such that the performing the claimed method steps would necessarily have the same result. That is, any method where the claimed methods steps are performed (such as in the method taught by Vannucchi et al.) would necessarily inhibit the generation of active thrombin on the surface of the cell.

Applicant is respectfully reminded that MPEP 2112.01 indicates, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are

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produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'"

Here, the claimed and prior art method steps are identical or substantially identical processes; therefore, a prima facie case of either anticipation or obviousness has been established.

***Allowable Subject Matter***

Claims 47-54 and 56-59 are allowed.

***Conclusion***

**Claim 62 is rejected.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

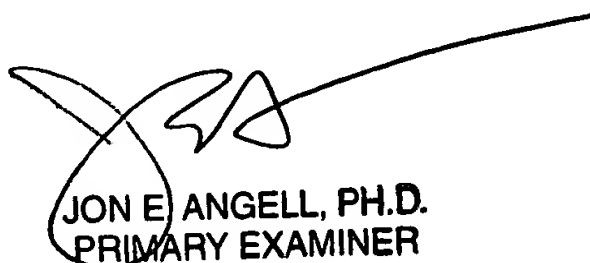
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JON E. ANGELL, PH.D.  
PRIMARY EXAMINER